

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 5970/S27

APPROVAL LETTER

NDA 5-970/S-027

Elkins-Sinn, Inc.
2 Estarbrook Lane
P.O. Box 5483
Cherry Hill, NJ 08034

AUG 24 1985

Attention: Thelma C. Hilibrand

Gentlemen:

Please refer to your supplemental new drug application dated February 14, 1983, resubmitted February 13, 1985, pursuant to section 505(b)(1) of the Federal Food, Drug and Cosmetic Act for Sotradecol (sodium tetradecyl sulfate) Injection.

The supplement provides for formula and procedures for a larger batch of purified gel (S-027).

We have completed our review of this supplement and it is approved. Please be advised that you must comply with the requirements set forth under 21 CFR 314.80 and 314.91 for an approved NDA.

Sincerely yours,

Patricia H. Russell, M.D.
Director
Division of Surgical-Dental
Drug Products
Office of Drug Research and Review
Center for Drugs and Biologics

cc: NDA 5-970

HFN-160

HFN-83

HFN-160/Rodriguez/Poochikian

Doc. Room 160

R/D: JPHannan 8/16/85

R/D init by PHRussell 8/21/85, CPHoiberg 8/20/85, GPoochikian 8/21/85

GBoyer 8/19/85, JCKenealy 8/21/85

FT td W2006Y 8/23/85

8-23-85

APPROVAL